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10/581,374

03/12/2007

Joseph C. Rongione

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EXAMINER

CUTLIFF, YATE KAI RENE

ART UNIT

PAPER NUMBER

1621

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,374	<b>Applicant(s)</b> RONGIONE ET AL.	
	<b>Examiner</b> YATE K. CUTLIFF	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2, 4 -6, 8, 10 - 20 & 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 4 -6, 8, 10 - 20 & 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 2, 4 -6, 8, 10 - 20 and 23 are pending.  
Claims 1, 3, 7, 9 and 21 - 22 have been canceled  
Claims 2, 4 -6, 8, 10 - 20 and 23 are rejected.

### ***Response to Amendment***

2. The amendment to claims 8, and 23, submitted December 16, 2010 is acknowledged and entered.

### ***Response to Arguments***

3. Applicant's arguments, see page 5, filed December 16, 2010, with respect to the 35 USC 112 second paragraph rejections of claims 8 and 23 have been fully considered and are persuasive in view of the arguments and amendment to claims 8 and 23. The 35 USC 112 second paragraph rejections of claims 8 and 23 have been withdrawn.
4. Applicant's arguments filed December 16, 2010, with regard to the 35 USC 103 (a) rejection of claims 23 and 2, 4-6, and claims 8 and 10 - 20 have been fully considered but they are not persuasive for the reason set out in the Office Action mailed July 16, 2010 and as set out below.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 23 and 2, 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knoer (US 3,644,179), in view of Cosgrove et al. (US 5194,640) and further in view of Ghisalberti et al. (WO 2001/1816), Reaney et al. (US 6,420,577) and Saebo et al. (US 6,410,761); for the reasons set out in the Office Action of July 16, 2010 and as set out below.

9. Applicant respectfully asserts that because Knoer relates to a process for distilling crude tall oil to improve the yield of rosin acids and fatty acids by the removal of the constituents of phenols and terpene alcohols (light ends) and wax alcohols (heavy

Art Unit: 1621

ends), which are substances prone to react at high temperature with the rosin acids and fatty acids of the tall oil; his process would not aid one of skill in the art seeking to improve the yield of desirable isomers of conjugated linoleic acids. Specifically, stating that the problem being solved by Knoer, removal of reactive components that are known to react with the desirable end product at high temperatures needed for distilling the desirable end products, differs from the problem Applicant is intending to solve by the claimed process. The problem being solved by Applicant's process is: "How to remove temperature stable side products that are not reactive with the desired end product where the desired end product itself is not temperature stable?".

In response, it is noted that claim 23 does not teach the removal of side products. Claim 6 discloses the removal of side products, but, the claim does not teach that the side products are temperature stable. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. (In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993)). In the instant case, claims 23, neither 6 nor the specification provide teaching that the side products are temperature stable. The specification merely teaches that side products are removed. Also, the specification teaches that Applicant's process obtains superior conjugated linoleic acid esters (CLA esters), but, does not disclose that the superior CLA ester is related to a certain temperature. Thus, one having ordinary skill in the art, viewing the teaching of Knoer, would expect to be able to obtain superior CLA ester composition having the characteristics disclosed in the specification after carrying out the process of

Art Unit: 1621

Knoer, since liked the claimed invention Knoer combines a thin film evaporator with a fractionating column.

Furthermore, the fact that Knoer uses the combination of the evaporator and fractionation/rectification column for a different reason than applicants does not mean that the applicant's process is unobvious. See MPEP 2144. IV. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323, 76 USPQ2d 1662, 1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) (discussed below).\*\* In *In re Linter* the claimed invention was a laundry composition consisting essentially of a dispersant, cationic fabric softener, sugar, sequestering phosphate, and brightener in specified proportions. The claims were rejected over the combination of a primary reference which taught all the claim limitations except for the presence of sugar, and secondary references which taught the addition of sugar as filler or weighting agent in compositions containing cationic fabric softeners. Appellant argued that in the

Art Unit: 1621

claimed invention, the sugar is responsible for the compatibility of the cationic softener with the other detergent components. The court sustained the rejection, stating "The fact that appellant uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be [sic, would have been] prima facie obvious from the purpose disclosed in the references." 173 USPQ at 562.

10. Applicant respectfully asserts that Ghisalberti only concerned with techniques for purifying an already obtained CLA product to remove minor impurities, where as Knoer is concerned with refining crude oil product containing major reactive species.

Additionally, Applicant respectfully asserts that Ghisalberti does not disclose a process for preparing CLA esters.

In response, the Examiner disagrees with Applicant's understanding of the teaching of Ghisalberti. On page 4 of Ghisalberti, it is disclosed: "the term CLA is intended to include either CLA in the form of free fatty acid or its derivatives, such as its phospholipid, its mon-, di- and triglycerides, ethers, esters or salts thereof. As such, the process of Ghisalberti applies to CLA esters. Further, as set out in the Office Action mailed July 16, 2010, Ghisalberti discloses that high grade CLA (i.e. CLA esters) can be further refined by conventional techniques that were known in the art at the time of the Ghisalberti process. Knoer's distillation process was one such refining technique known in the art at the time of Ghisalberti's teaching. Thus, In light of the limited refining methods available for refining compositions containing CLA or its alkyl esters, without causing reactions to occur during the refining process, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to try and

refine compositions containing CLA or CLA alkyl esters of Ghisalberti, by the process taught by Knoer et al. in an attempt to increase yield, and reduce the formation of products produced by prolonged heating during distillation, because one of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common senses.

11. Applicant respectfully asserts in the arguments relating to Saebo and Raney focuses on the teaching in Saebo that their distillation takes place for less than one minute. Further, asserting that their CLA ester stream in the rectification column is on the order of 30 minutes, which is significantly greater than the less than one minute exposure to elevated temperatures disclosed by Saebo. Further, Applicant reasserts the March 13, 2009 affidavit of Dr. Rongione.

In response, the Examiner's understanding of Saebo is that it teaches that elevated temperatures between 180 and 200°C for up to several hours should be avoided. Applicant's claimed invention does not specify a set time for their distillation process. Applicant in the current set of arguments sets forth a limitation regarding the residence time for the distillation step that is not in the claims nor does the specification teach or disclose a residence time in the order of 30 minutes. Applicant is arguing a limitation that is not claimed or disclosed. Applicant's specification discloses that the distillation apparatus is a low residence time distillation apparatus. Saebo's process suggests distillation with a low residence time, specifically a time should not be at high temperatures for several hours. In response to Applicant's reassertion of the affidavit,



the Examiner's previous comments, in the Office Action mailed July 2, 2009 are set out below.

The Declaration under 37 CFR 1.132 filed March 13, 2009 is insufficient to overcome the rejection of claims 1, 2 and 4-20 based upon 35 U.S.C. 103(a) rejections as set forth in the last Office action because: Applicant directs Examiner to Example 1 in Applicant's Specification. It is stated in the Declaration that this example illustrates a molecular distillation process similar to the process used in Saebo et al. (US 6,410,761). It is noted that in Example 1, the temperature ranges are 120 to 125°C and with the apparatus being a low residence time distillation apparatus. However, in Example 1, one skilled in the art would presume that each distillation pass is conducted at a temperature well below the temperature 190°C used in the Saebo et al. patent. Further, in Saebo et al. the distillation is conducted in less than one minute. Applicant's Example 1 does not provide data as to the amount of time involved in the distillation process. Additionally, the Saebo et al. patent only discourages conducting the distillation process at elevated temperatures between 180 and 200°C over an extended period of time, i.e. several hours.

Applicant, even compared the results of Example 1 with the Results of Example 6 of their specification, however, no time was given in Example 6. From the discussion in both the Saebo patent and Applicant's Exhibit A, residence in conjunction with temperature has an affect on outcome of the refining process. Thus, based on the lack of information provided in Applicant's Example 1 when compared to Saebo et al.

Art Unit: 1621

(closest prior art), it is not clear to the Examiner that the results of the process are unexpected.

Therefore, for the reasons set out above and as set forth in the Office Action mailed July 16, 2010 claims 23 and 2, 4-6 are considered to be prima facie obvious.

12. Claims 8, and 10 - 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saebo et al. (US 6,410,761), in view of Knoer (US 3,644,179), in view of Baltes et al. (US 3,162,658), in view of in view of Cosgrove et al. (US 5,194,640), in view of Reaney et al. (US 6,420,577), in view of Kirk-Othmer (4th edition, vol. 10, 1993) and further in view of Sachtler (US 5,326,925); for the reasons set out in the Office Action of July 16, 2010 and as set out below.

13. Applicant respectfully asserts that neither Saebo, alone or in combination with Knoer, Cosgrove, and Reaney, suggest the use of a thin film or wiped-film evaporator connected to a fractionating column to distill a CLA ester stream to increase the amount of desirable c9,t11 and t10,c12 CLA isomers, as required by amended claim 8. Additionally, asserting that Saebo provides no suggesting or motivation to one having ordinary skill in the art to couple the molecular distillation system to a rectification column.

14. Further, Applicant basically reasserts that because Knoer relates to a process for distilling crude tall oil to improve the yield of rosin acids and fatty acids by the removal of the constituents of phenols and terpene alcohols (light ends) and wax alcohols (heavy ends), which are substances prone to react at high temperature with

Art Unit: 1621

the rosin acids and fatty acids of the tall oil; his process would not aid one of skill in the art seeking to improve the yield of desirable isomers of conjugated linoleic acids.

Specifically, stating that the problem being solved by Knoer, removal of reactive components that are known to react with the desirable end product at high temperatures needed for distilling the desirable end products differs from the problem Applicant is intending to solve by the claimed process. That problem being: "How to remove temperature stable side products that are not reactive with the desired end product where the desired end product itself is not temperature stable?".

15. In response, the Examiner notes that Saebo's process prepares CLA esters in accordance with the Applicant's first two refining steps of claim 8, and teaches one form of distillation that is like-unto a thin film or wiped-film evaporator. Also, it is noted that claim 8 does not teach the removal of side products. Claim 19 discloses the removal of side products, but, the claim does not teach that the side products are temperature stable. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. (In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993)). In the instant case, Applicant's claims 9, 19, nor the specification provide teaching that the side products are temperature stable. The specification teaches that side products are removed. Also, the specification teaches that Applicant's process obtains superior conjugated linoleic acid esters (CLA esters), but, does not disclose that the superior CLA ester is related to a certain temperature. Thus, one having ordinary skill in the art, viewing the teaching of Knoer, would expect to be able to obtain superior CLA ester composition having the characteristics disclosed in

Art Unit: 1621

the specification after carrying out the process of Knoer, since like the claimed invention Knoer combines a thin film evaporator with a fractionating column.

Furthermore, with regard to the arguments set forth regarding the combining of Knoer with Saebo; the fact that Knoer uses the combination of the evaporator and fractionation/rectification column for a different reason than applicants does not mean that the applicant's process is unobvious. See MPEP 2144. IV. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323, 76 USPQ2d 1662, 1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) (discussed below). In *In re Linter* the claimed invention was a laundry composition consisting essentially of a dispersant, cationic fabric softener, sugar, sequestering phosphate, and brightener in specified proportions. The claims were rejected over the combination of a primary reference which taught all the claim limitations except for the presence of sugar, and secondary references which taught the addition of sugar as a filler or weighting

Art Unit: 1621

agent in compositions containing cationic fabric softeners. Appellant argued that in the claimed invention, the sugar is responsible for the compatibility of the cationic softener with the other detergent components. The court sustained the rejection, stating "The fact that appellant uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be [sic, would have been] prima facie obvious from the purpose disclosed in the references." 173 USPQ at 562.

Therefore the reasons set out above claims 8 and 10 – 20 are considered to be prima facie obvious.

### ***Conclusion***

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:30 p.m.

Art Unit: 1621

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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